

Director

Department of Pesticide Regulation



DEPARTMENT OF PESTICIDE REGULATION PESTICIDE REGISTRATION AND EVALUATION COMMITTEE Meeting Minutes – November 18, 2005 (amended)

Committee Members/Alternates in Attendance:

Anna Fan, Office of Environmental Health Hazard Assessment (OEHHA)

Charlie Goodman, Department of Food and Agriculture (CDFA)

Syed Ali, State Water Resources Control Board (SWRCB)

Dave Whitmer, County Agriculture Commissioners and Sealers Association (CACSA)

Brian Larimore, Integrated Waste Management Board (IWMB)

Lynn Baker, Air Resources Board (ARB)

Barry Wilson, University of California Department of Environmental Toxicology (UCD)

Ray Chavira, U.S. Environmental Protection Agency, Reg. 9 (USEPA)

Rebecca Sisco, University of California IR-4 Program

Brian Finlayson, Department of Fish and Game (DFG)

Tobi Jones, Department of Pesticide Regulation (DPR)

Visitors in Attendance:

Denise Webster, DPR

Joyce Gee, DPR

Mark Rentz, DPR

Glenn Brank, DPR

Brian Bret, Dow Agro Sciences

John Inouye, DPR

Kevin Keefer, Western Plant Health Association (WPHA)

Artie Lawyer, Technical Sciences Group (TSG)

Colleen Stanney, Inside Cal/EPA

John Pearson, Compliance Services

Bill Fabre, DPR

David Supkoff, DPR

Liz Pelham, DPR

Marshall Lee, DPR

Nan Singhasemanon, DPR

Frank Spurlock, DPR

Ann Prichard, DPR

Kay Newhart, DPR

Jon Shelgren, DPR

Dennis Fortner, Rydean Molded Products

John Lublinkhof, Bell Laboratories, Inc.

John Hott, Syngenta

1001 I Street • P.O. Box 4015 • Sacramento, California 95812-4015 • www.cdpr.ca.gov



Zhimin Lu, Regional WQCB-R5
William S. Feil, Ph.D., Land for Urban Wildlife Inc.
Helene Feil, Ph.D., Land for Urban Wildlife Inc.
Steve Wallauolt, Lynn M Stater & Assoc. (Ventura County)
Martha Harnly, DHS-EHIB
Anne Katten, CRLAF
Paul Hann, RWQCB-R5
Patricia Gouveia, SWRCB
Roberta Firoved, CA Rice Commission
Dave Tamayo, CASQA
Randy Pollak, Greenberg & Traurig
Nate Solov, Assemblywoman Fran Pavley's office
Geoff Brosseau, CASQA

- 1. <u>Introductions and Committee Business</u> Tobi Jones, Chairperson
 - a. About 46 people attended the meeting.
 - b. There were no corrections to the minutes of the previous meeting held on September 16, 2005.
- 2. <u>Registration Requirements for Assessing Aquatic Toxicity with Focus on Pyrethroids</u> Jon Shelgren, Registration Branch, and Kaylynn Newhart, Environmental Monitoring (EM) Branch

This item was based on a request by Syed Ali for a presentation of DPR's data review process for aquatic and sediment fate and toxicity, with reference to permethrin. Jones introduced this topic with background on DPR's use of USEPA data requirements to determine DPR's requirements for specific products. Jones indicated that if DPR receives data or, through monitoring, develops data that identifies issues with pesticide behavior, DPR uses its reevaluation process to gather additional data to characterize the problem more fully, or request data to show how a problem would be addressed.

Jon provided background on the use of aquatic toxicity data to assess pesticide products prior to USEPA's data requirements established in 1984. Jon then discussed the current requirements, covering species tested, duration and use of endpoints, and how they are used in product review. He provided some examples of study results for a sample pyrethroid. Jon compared the current data requirements to USEPA's proposed revisions of requirements for testing aquatic vertebrates and invertebrates, including use of screening criteria for further testing based on physical/chemical properties, and further toxicity testing of whole sediment on invertebrates. Kaylynn discussed how certain registration packages are routed to EM for review, particularly as it relates to surface water concerns. The review program has evolved with the evolution of surface water concerns; that is, EM's earlier focus on rice pesticides has

evolved to all aquatic use pesticides, and more attention is now focused on pesticide runoff concerns. EM may consult with Department of Fish and Game, and the waterboards depending on the use and the data. Kaylynn discussed areas of review, including the environmental hazards statements on USEPA-approved labels that may not mitigate all impacts, and several conditions of use that may affect behavior of both the active ingredient and its metabolites. Other outside sources of information may be considered as well, and EM may request additional data to better characterize potential problems identified. Both Kaylynn and Jon identified the importance of the recent Westin studies in identifying new issues with sediment toxicity of pyrethroids. Jones indicated that EM has recently requested a reevaluation of all pyrethroid-containing products based on recent data pertaining to sediment toxicity.

There was discussion by the committee and members of the audience following the presentations. Jon clarified that required studies are based on testing of active ingredients, not formulated products, so that specific product use is not a governing factor. Kaylynn described circumstances where consultation with other state agencies during the registration process was important. Syed Ali identified other forums where water issues may be addressed between DPR and the state and regional waterboards. Concerns were raised that data requirements may not address accumulation in sediment over time, as appears to be the case with pyrethroids. Ray Chavira discussed USEPA's approach under reregistration of conducting use analysis as a means of better addressing urban water issues, and mentioned analysis of permethrin's potential impact in publicly owned treatment works (POTWs) as the result of washing treated clothing. Members of the audience with responsibility for stormwater management spoke about their interest in having DPR address concerns with pyrethroids, as they appear to be replacing diazinon and chlorpyrifos as consumer use insecticides. There was also expressed interest in using urban runoff models and whole product testing in more comprehensive assessment of products prior to registration.

3. Status of Brodifacoum Reevaluation – Jon Shelgren, DPR Registration Branch,

Jones introduced this item as a consultation with the committee on the scientific issues supporting the staff recommendations on the brodifacoum reevaluation. (The committee had been provided a background paper on this subject prior to the meeting). Jones indicated that DPR had met several times with the Rodenticide Task Force, and had agreed to defer any DPR action until USEPA had acted. However, given the public's interest in wildlife issues associated with brodifacoum this year and the length of time USEPA had taken to act, DPR wanted to move ahead to begin to take steps to mitigate what it believes to be problems with current uses of brodifacoum and two related anticoagulants. Jones clarified that this consultation is a first step, and that DPR will provide registrants the opportunity to provide input on mitigation measures that will address the problem.

Jon Shelgren reviewed background on the issue and what led to his recommendations. The following is a summarization of the paper provided to the committee:

The anticoagulant rodenticide brodifacoum, currently marketed as "D-Con" Rat Bait, was developed by Hadler and Shadbolt (1975) for use against Warfarin-resisitant rodents. Brodifacoum, along with the closely related bromadiolone and difethialone, are classified as the 2nd generation anticoagulant rodenticides. Warfarin, fumarin, pival, diphacinone, chlorophacinone, etc., are the 1st generation anticoagulant rodenticides. Second generation rodenticides are hydrophobic, lipophilic and the target rodent receives a delayed lethal dose with the first feeding. At the time of death, the rodent has a significant "body burden" of this persistent pesticide. Rodents ingesting the 1st generation anticoagulant rodenticides must continually consume the bait in order to receive a lethal amount (4-5 days).

Brodifacoum has been implicated in wildlife losses in several states and foreign countries. In California, it is used exclusively for urban rodent species. Brodifacoum is a "General Use" product, not a "Restricted Material" and can be purchased by the general public at numerous locations.

The Pesticide Investigations Unit of the California Department of Fish and Game (CDFG) requested in 1999 that the DPR place products containing brodifacoum into reevaluation. Regulatory actions in California could range from canceling the registration to a minor label change or to restrict the use of brodifacoum licensed Pest Control Operators. In both laboratory and field studies, reducing the amount of active ingredient from 50 ppm to 10 ppm significantly reduced the whole body residues in target animals (voles). A six fold reduction in these residues brings most target animal residues below scavenger LD₅₀ values. Alternative rodenticides to brodifacoum, difethialone and bromadialone are diphacinone, chlorophacinone, fumarin, warfarin and pival, the non-anticoagulants cholecalciferol, bromethalin and the Restricted Use zinc phosphide.

Jon's Recommendations:

- 1) Restrict the use of rodenticide baits containing brodifacoum, difethialone and bromadialone to "indoor structural use only" and eliminate the current label use sites that allow for use "around homes, industrial, commercial, agricultural and public buildings" and "around transport vehicles (ships, trains, aircraft) and related port or terminal buildings." Tamper- proof bait box use for these rodenticides should be indoors used where children and/or pets could be at risk of exposure. This recommendation is in compliance with the letter from CDFG (6/12/2003).
- 2) Consider "Restricted Material" status for these three rodenticides should recommendation #1 prove ineffective in reducing nontarget wildlife losses.

The committee discussed several aspects of these recommendations. Whether labels allowing indoor use only was enforceable, and whether homeowners would be responsible users (to

follow such label restrictions) was the first issue. Dave Whitmer indicated that counties can take action against individuals for not following label directions, and also thought that DFG might have some enforcement authority when some nontarget species are affected. Committee members pointed to problems with urban water quality as an example of questionable homeowner responsibility for following label directions.

There was discussion of how DPR would know if labeling changes were successful, eg. monitoring results of changing the delivery system and labeled uses. Brian Finlayson expressed concern about not having data to judge the value of a change because of lack of resources for investigations on anticoagulant poisoning. Whitmer discussed potential opportunities using veterinarians that see injured wildlife as a means of data collection, and Barry Wilson spoke to the potential of using the UC Davis Veterinary School wildlife unit.

Finlayson brought up reducing the concentration of active ingredient as another option for DPR to consider, indicating that the current concentration is twice as high as needed for effectiveness. However, there is limited data on exposure of prey at these lower concentrations.

There was discussion of DPR carefully considering unintended consequences of changing use patterns. Whitmer commented on the restricted material option, and counties handling permit requests from homeowners. He indicated that a thorough discussion of the issues should occur at the next meeting of the commissioners in February. Whitmer also commented on potential impacts on levee maintenance if availability of rodent control materials is limited. Finlayson cautioned about shifting uses back to first generation anticoagulants and the impact it may have on nonpoisonous tainting of game meat. Shelgren clarified that the second generation rodenticides are more effective because of the treatment regime.

Ray Chavira indicated that USEPA Region 9 would urge action by USEPA headquarters given the heightened concern about labeling and use of these rodenticides in California.

Members of the audience provided comments following the committee discussion. Registrant representatives expressed concern about lumping all three of the active ingredients together while incidents have only identified brodifacoum. Shelgren clarified that DFG tissue analysis has identified all 3 compounds, and indicated concern about shifting use and problems from one material to a second if DPR only focused on brodifacoum. Representatives indicated that USEPA is very close to announcing the results of their review. They also brought up the issue of safety to children because of availability of an antidote (vitamin K) for this class of chemistry that is not effective against other classes of rodenticide chemicals. [Clarification: Jones received external comments after minutes were made available that vitamin K serves as an antidote for any anticoagulant rodenticide, whether 1st or 2nd generation material, but is not an antidote for non-anticoagulant rodenticides.] They believe that expanded use of

bittering agents will further deter children from ingesting. Registrants expressed concern that limiting use to pest control operators would limit homeowners' access to these rodenticides that serve a public health benefit, particularly in urban areas. They indicted their support for product stewardship in order to assure proper usage. They felt that Shelgren's use of certain references was inaccurate, and/or not relevant to the California discussion. There was some acknowledgement that issues associated with nontarget poisoning events needed to be addressed.

Other members of the audience supported action by the committee. Representatives from Assemblywoman Pavley's office and the Ventura Board of Supervisors expressed support for making these rodenticides restricted materials, and commented on their interest in this problem. A representative for Land for Urban Wildlife spoke of concern for broadcast application of any rodenticide-containing grain bait, and supported limiting use to indoors.

4. <u>Risk Assessment Prioritization List Report #47</u>- Joyce Gee, DPR Medical Toxicology Branch

The Prioritization and Status of Active Ingredients for Risk Characterization: Report #47, November 18, 2005, was distributed to the PREC at the meeting. Items of interest were the change in contact for questions to Joyce Gee, the removal of sulfuryl fluoride from the list, the new additions in italics and the assignment of sodium tetrathiocarbonate for the initiation of the risk assessment.

5. Risk Assessment Process- Jay Schreider, DPR Medical Toxicology Branch

Jay Schreider gave a description of the DPR risk assessment process. Jay described the internal processes DPR uses to prepare and review a Risk Characterization Document (RCD), to release the RCD for external review, to seek external review, especially OEHHA peer review, to respond to the comments, to revise the RCD, and to develop subsequent addenda to the completed RCDs. Jay provided a flowchart to illustrate the process. A request was made to place the flowchart on the DPR website; however, Jay and Tobi Jones indicated that the chart was in draft form. There was discussion about when RCD addenda are reviewed by OEHHA and whether there are timeframes for different steps in the process to help OEHHA in its planning. Both Jay and Tobi noted that assigning hard timeframes is not possible because toxicologists conducting the risk assessments are working on several chemicals at once, and available data for each chemical are variable. Jones indicated that over that last few years, OEHHA had been able to provide peer review comments in a timely manner.

6. Agenda Items for Next Meeting-Tobi Jones, DPR

A status report on the new active ingredient aminopyralid was requested. The next meeting will be held on Friday, January 20, 2006 in the Sierra Hearing Room located on the second floor of the Cal/EPA building.

7. <u>Closing Comments</u> – Tobi Jones

The meeting was adjourned.